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11.0 510(k) Summary of Safety and Effectiveness

This Special 510(k) submission notifies the FDA of our intention to introduce the M2636B TeleMon B Monitor--an upgraded version of the current M2636A TeleMon, which is an extension device for the M2600A Telemetry System.

11.1 Manufacturer/Submitter

Denise Haley
Quality and Regulatory Affairs Engineer

Agilent Technologies, Incorporated
Patient Monitoring Division
Healthcare Solutions Group
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11.2 Establishment Registration Number

1218950

11.3 Manufacturing Site Address

Agilent Technologies, Incorporated
Patient Monitoring Division
Healthcare Solutions Group
3000 Minuteman Road
Andover, MA 01810-1099

11.4 Sterilization Site

Does not apply.

11.5 Date

June 8, 2001

11.6 Device Name, Trade Name

Proprietary Name: Agilent M2636B TeleMon B Monitor (TeleMon B)

Common Name: Multi-Parameter Portable Patient Monitor

[This device uses the M2601A Agilent (Viridia) Transmitter, a component of the Agilent M2600A Telemetry System.]

Component Classifications:

Device classification information is presented in the following table. The FDA has placed all devices with arrhythmia and alarm capability in Class III. The

Table 1: Panel 74, Cardiovascular

Classification	Procode	Description	Tier
870.2300	DRT	Monitor, Cardiac	2
870.1025	DSI	Detector and Alarm, Arrhythmia	3
870.2340	DPS	Electrocardiograph	2
870.1110	DSK	Computer, Blood Pressure	2
870.1120	DXQ	Cuff, Blood Pressure	2
870.1130	DXN	System, Measurement, Blood-Pressure, Non-Invasive	2

11.7 Performance Standards

Mandatory Standards:

21 CFR Part 898 establishes a performance standard for electrode lead wires and patient cables, and for arrhythmia detectors and alarms for the procodes and device classifications contained in the system and codified at 870.1025. This component of the Agilent M2636B TeleMon is unchanged from the previous submission for the M2600A Telemetry System and Viridia/Agilent Information System, and remains compliant. These components were previously cleared for commercial use in Premarket Notification K000854 (cleared April 3, 2000), K993516 (cleared November 8, 1999), K980429 (cleared September 9,1998), and K991773 (cleared June 7, 1999).

11.8 Substantial Equivalence

The Agilent M2636B TeleMon B Monitor is substantially equivalent to the previously cleared devices listed below:

Manufacturer	Device	Model	510(k)
Agilent Technologies, Inc.	M2636A TeleMon Monitor	M2636A	K001436
Hewlett Packard/Agilent Technologies	Viridia Information Center Software for M3150A and M3153A, and Viridia Telemetry	M315x, M2600A	K000854
Hewlett Packard/Agilent Technologies	HP M2600A Viridia Telemetry System	M2600A	K993516
Hewlett Packard/Agilent Technologies	Viridia HP M3000A/M3046A (M3/M4)	M3000A M3046A	K991773
Hewlett Packard/Agilent Technologies	HP Models M3000A/M3046A Patient Monitor	M3000A M3046A	K981576
Hewlett Packard/Agilent Technologies	Viridia Wave Viewer	M2605A	K974567
Hewlett Packard/Agilent Technologies	Detector and Alarm, Arrhythmia	(see M315x , M30xx, M2600)	K964122
Hewlett Packard/Agilent Technologies	HP M1175A, M1176A Component Monitoring System	M1175A, M1176A	K941811

11.9 Modification Description

The modification in this submission is the addition of audible alarms, the display of pulse and PVC rate numerics, a software upgradeable NBP module with improved measurement time, and the addition WaveViewer functionality to the M2636A TeleMon B Monitor, a multi-parameter monitor as an extension to the M2600A Telemetry System. The new device will be known as the M2636B TeleMon B Monitor

11.10 Intended Use

TeleMon is indicated for use in the monitoring, recording, and alarming of multiple physiologic parameters in adult and pediatric patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

TeleMon is a prescription devices for use in healthcare facilities by trained healthcare professionals. TeleMon is not intended for home use.

11.12 Fundamental Technology

The fundamental scientific technology employed in the operation of this device has not changed from the predicate devices [K001436 (cleared June 7, 2000), K000854 (cleared April 3, 2000), K993516 (cleared November 8, 1999), K980429 (cleared September 9,1998), and K991773 (cleared June 7, 1999)].

11.13 Design Controls

Verification, validation, and testing activities will be successfully conducted prior to commercialization to establish the safety, performance, and reliability characteristics of the M2636B TeleMon B Monitor. Testing involves system level tests, integration tests, safety tests from hazard analysis, interference testing, and hardware testing. Pass/fail criteria are based on the specifications cleared for the predicate devices to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2001

Ms. Denise Haley
Quality and Regulatory Approvals Engineer
Healthcare Solutions Group
Patient Monitoring Division MS 0490
Agilent Technologies, Inc.
3000 Minuteman Road
Andover, MA 01810-1099

Re: K011824
Trade Name: Agilent M2636B TeleMon B Monitor
Regulation Number: 21 CFR 870.1025
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: June 8, 2001
Received: June 11, 2001

Dear Ms. Haley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

3.1 ODE Indications for Use Statement

Indications for Use Statement

510(k) Number: K011824
(if known)

Device Name: Agilent M2636B TeleMon B Monitor

Indications for Use:

TeleMon is indicated for use in the monitoring, recording, and alarming of multiple physiologic parameters in adult and pediatric patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011824